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Sub	ostitute for form 1449/PTO			Complete if Known		
				Application Number	10/811,839	
IN	<b>IFORMATION</b>	I DI	SCLOSURE	Filing Date	March 30, 2004	
S	TATEMENT E	3Y /	APPLICANT	First Named Inventor	Theoharis C. THEOHARIDES	
				Art Unit	1615	
	(Use as many sheets as necessary)			Examiner Name	C. S. Hagopian	
Sheet	1	of	6	Attorney Docket Number	2003133.00125US11	

			U.S. PA	TENT DOCUMENTS		
Examiner Cite		Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where	
Initials*	No.1	Number-Kind Code <sup>2</sup> ( if known)	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear	
	AA*	US-20070141187	06-21-2007	Theoharides		
	AB*	US-20050220909	10-06-2005	Theoharides		
	AC*	US-6,136,795	10-24-2000	Florio		
	AD*	US-5,876,744	03-02-1999	Della Valle et al.		
	AE*	US-6,162,787	12-19-2000	Sorgente et al.		
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	AG*	US-20010000340	04-19-2001	Chen et al.		
	AH*	US-20020146393	10-10-2002	Bell et al.		
	AI*	US-20060210551	09-21-2006	Lindsberg et al.		
	AJ*	US-5,223,257	06-29-1993	Arora		
	AK*	US-5,250,529	10-05-1993	Theoharides		
	AL*	US-5,260,335	11-09-1993	Wagner et al.		
	AM*	US-5,648,355	07-15-1997	Theoharides		
	AN*	US-5,795,905	08-18-1998	McCarthy et al.		
	AO*	US-5,804,594	09-08-1998	Murad		
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	AQ*	US-5,980,865	11-09-1999	Ahmed		
	AR*	US-5,994,357	11-30-1999	Theoharides		
	AS*	US-6,020,305	02-01-2000	Theoharides		

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Examiner	Cite	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines,				
Initials* No.		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Date MM-DD-YYYY		Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>			
	ВА	WO-199833494	08-06-1998	Kosbab					
	ВВ	WO-200078320	12-28-2000	Joint Juice Inc.		П			
	вс	GB-2105193	09-12-1984	Glaxo Group Ltd.					
	BD	EP-0426479	05-08-1991	McNeil-PPC, Inc.					

Examiner Signature	/Casey Hagopian/	Date Considered	01/28/2010
Olgitataic		Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1,98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁴ Applicant is to place a check mark here if English language Translation is attached.

Receipt date: 09/11/2009 10811839 - GAU: 1615

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	AT*	US-6,211,195	04-03-2001	Webb et al.	
	AU*	US-6,586,448	07-01-2003	DeNinno et al.	
	AV*	US-6,689,748	02-10-2004	Theoharides	
	AW*	US-6,765,008	07-20-2004	Chen	

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		NON PATENT LITERATURE DOCUMENTS					
Examiner Initials <sup>*</sup>	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>				
	CA	International Search Report and Written Opinion, International Patent Application No. PCT/US08/86059, mailed 26 January 2009 (2 pages)					
	СВ	Russell, A.L. and McCarty, M.F. "Glucosamine for migraine prophylaxis?" Medical Hypotheses, 55(3): 195-198 (2000)					
	СС	Matsuda, K. et al., "Inhibitory Effects of Sialic-Acid- or N-Acetylglucosamine-Specific Lectins on Histamine Release Induced by Compound 48/80, Bradykinin and a Polyethylenimine in Rat Peritoneal Mast Cells," Jpn. J. Pharmacol., 64: 1-8 (1994)					
	CD	Trichonoulou, A. et al. "Concor and Meditarrangan Dietary Traditions." Concor Epidemiology					
	CE	Theoharides, T.C., "The Mast Cell: A Neuroimmunoendocrine Master Player," Int. J. Tiss. Reac. XVIII(1), 1-21 (1996)					
	CF	Theoharides, T.C., "Histamine2 (H2)-Receptor Antagonists in the Treatment of Urticaria," Drugs 37: 345-355 (1989)					
	CG	Theoharides, T. "Mast Cells and Migraines," Brief Proposal, (1983)					
	СН	Morrow, J. et al., "Indentification of Skin as a Major Site of Prostaglandin D2 Release Following Oral Administration of Niacin in Human," J. Invest. Derm., Vol. 98(5): 812-815 (1992)					
	CI	Weston, A. et al., "Terminal Ileal Mucosal Mast Cells In Irritable Bowel Syndrome," Dig. Diseases and Sci., Vol. 38(9): 1590-1595 (Sept. 1993)					
	CJ	Shapiro, G. et al., "Cromolyn Sodium: A Review," Pharmacotherapy, Vol. 5(3): 156-170 (May/June 1985)					
	СК	Database WPI: 2001-358435 - XP002221703, "Compositions comprising hyaluronic acid and flavonoids," (2 pages)					
	CL	International Search Report issued for PCT/US02/00476, dated December 16, 2002 (6 pages)					
	СМ	Parodi et al., Arch. Psicol. Neurol. Psichiatr. Vol. 49(3): 299-303 (1988)					
	CN	Split et al., "Ketotifen in the Treatment of Chronic Cluster Headache," Headache, Vol. 24(30: 147-148: 1984)					
	CO	Unlisted Drugs, Vol. 20(11): 167 (November 1968)					
	СР	Debeuckelaere, et al., "Systemic Mast Cell Disease: A review of the literature with special focus on the gastrointestinal manifestations", Acta clinica Belgica, 46, 226-232 (1991)					
	CQ	Koblenzer, C.S. "Neurotic excoriations and dermatitis artefacta," Dermatologic Clinics, Vol. 14(3): 447-455 (July 1996)					

Examiner Signature	/Casey Hagopian/	Date Considered	01/28/2010
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<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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Sheet	4	of	6	Attorney Docket Number	2003133.00125US11	

Examiner	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of	T2
Initials <sup>*</sup>	No. <sup>1</sup>	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	
	CR	Tauberg, J. et al., "Stress-induced urticaria associated with local anesthetic administration," Anesthesia Progress, Vol. 30(6): 199-200 (1983)	
	cs	Theoharides, T.C. "Mast Cells: The Immune Gate To The Brain," Life Sciences, Vol. 46: 607-617 (1990)	
	СТ	Lambracht-Hall, M. et al., "Serotonin Release From Rat Brain Mast Cells In Vitro," Neuroscience, Vol. 39(1) 199-207 (1990)	
	CU	Dimitriadou, V. et al., "HISTOCHEMICAL AND ULTRASTRUCTURAL CHARACTERISTICS OF RAT BRAIN PERIVASCULAR MAST CELLS STIMULATED WITH COMPOUND 48/80 AND CARBACHOL, Neuroscience, Vol. 39(1): 209-224 (1990)	
	CV	Pearce, F.L. "Mast cell heterogeneity," TIPS: 165-167 (April 1983)	
	cw	Theoharides, T.C. and Douglas, W.W. "SOMATOSTATIN INDUCES HISTAMINE SECRETION FROM RAT PERITONEAL MAST CELLS," Endocrinology, Vol. 102(5): 1637-1640) (Nov. 7, 1977)	
	СХ	Sundaram, K. et al., "Antagonists of luteinizing hormone releasing hormone bind to rat mast cells and induce histamine release," Agents and Actions, Vol. 25(3/4): 307-313 (1988)	
	CY	Prior, A. and Read, N.W. "Reduction of rectal sensitivity and post-prandial motility by granisetron, a 5HT3 receptor antagonist, in patients with irritable bowel syndrome (IBS)," Brit. Soc. of Gasteroent., A1174	
	CZ	Mathias, J. et al., "Debilitating 'Functional' Bowel Disease Controlled by Leuprolide Acetate, Gonadotropin-Releasing Hormone (GnRH) Analog," Digestive Diseases and Sciences, Vol. 34(5): 761-766 (May 1989)	
	CA1	Read, N.W. "Irritable bowel syndrome (IBS)definition and pathophysiology,", Vol. 130: 7-13 (1987)	
	CB1	Stefanini, G.F. et al., "Oral disodium cromoglycate treatment on irritable bowel syndrome: An open study on 101 subjects with diarrheic type," Vol. 87: 55-57 (1992)	
	CC1	International Search Report issued for PCT/US95/01392, dated May 31, 1995 (4 pages)	
	CD1	Hendriks, J. et al., "Flavonoids Influence Monocytic CTPase Activity and Are Protective In Experimental Allergic Encephalitis," J. Exp. Med., Vol. 200(12): 1667-1672 (2004)	
	CE1	Mezzapesa, D. et al., "Glatiramer acetate in multiple sclerosis," Expert Rev. Neurotherapeutics (5)4: 451-458 (2005)	
	CF1	Gupta, E. et al., "Lovastatin and Extended-Release Niacin Combination Product: The First Drug Combination for the Management of Hyperlipidia," Heart Disease, Vol. 4, 124-137 (2002)	
	CG1	Owens, M.J. and Nemeroff, C.B., "Physiology and Pharmacology of Corticotropin-releasing Factor," Pharmacological Reviews, Vol. 43(4): 425-615 (1991)	
	CH1	Devlin, Thomas (ed): Textbook of Biochemistry with Clinical Correlations, 2nd Edition: Ch. 8.5-8.6, 345-351 (1982)	

Examiner	(Cacay Haganian)	Date	04/00/0040
Signature	/Casey Hagopian/	Considered	01/20/2010

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		NON PATENT LITERATURE DOCUMENTS							
Examiner Initials	Cite No. <sup>1</sup>								
	CI1	Simopoulos, A.P., Visioli F. (eds): Mediterranean Diets. World Rev. Nutr. Diet. Basel, Karger, Vol. 87: 56-77 (2000)							
	CJ1	Urade, Y. et al., "The Major Source of Endogenous Prostaglandin D2 Production is Likely Antigen-Presenting Cells," J. Immunol., 143(9): 2982-2989 (Nov. 1, 1989)							
	CK1	Lidor, C. et al., "Osteoporosis as the Sole Presentation of Bone Marrow Mastocytosis," J. Bone Min Res., Vol. 5(8): 871-876 (1990)							
	CL1	Kimata, M. et al., "Effects of luteolin, quercetin and baicalein on immunoglobulin E-mediated mediator release from human cultured mast cells," Clin. and Exper. Allergy, Vol. 30, 501-508 (2000)							
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	CN1	Irani, A-M, et al., "Mast Cell Changes in Scleroderma," Arth. and Rheuma., Vol. 35(8): 933-939 (August 1992)							
	CO1	Dunn, R.T. et al., "Low-Dose Aspirin and Ibuprofen Reduce The Cutaneous Reactions Following Niacin Administration," Am. J. Thera., 2: 478-480 (1995)							
		Dvorak, A.M. et al., "Human Gut Mucosal Mast Cell: Ultrastructural Observations and							
	CP1	Anatomic Variation In Mast Cell-Nerve Associations in vivo," Int. Archives of Allergy & Immunology, Vol. 98: 158-168 (1992)							
	CQ1	Cefali, E.A. et al., "Aspirin reduces cutaneous flushing after administration of an optimized extended-release niacin formulations," Int. J. Clin. Pharm. Ther., Vol. 45: 78-88 (2007)							
	CR1	Verbeek, R. et al., "Oral flavonoids delay recoverly from experimental autoimmune encephalomyelitis in SJL mice," Biochem. Pharm., 70: 220-228 (2005)							
	CS1	Trichopoulou, A. et al., "Diet and Survival of Elderly Greeks: a link to the past1-4." Am. J. Clin. Nutri., Vol. 61(suppl.): 1346S-50S (1995)							
	CT1	Tsakalos, N, et al., "Induction of Mast Cell Secretion by Parathormone," Biochemical Pharmacology, Vol. 32(2): 355-360 (1983)							
	CV1	Theoharides, T. et al., "Bladder Mast Cell Activation in Interstitial Cystitis," Seminars of Urology, Vol. IX(2): 74-87 (May 1991)							
	CW1	Shoskes, D., et al., "Quercetin in men with category III chronic prostatis: a preliminary prospective, double-blind, placebo-controlled trial," Urology, 54(6): 960-963 (1999)							
	CX1	Seibold, J. et al., "Dermal Mast Cell Degranulation in Systemic Sclerosis," Arth. and Rheuma., Vol. 33(11): 1702-1709 (Nov. 1990)							
	CY1	Rockoff, S.D. and Armstrong, J.D. "Parathyroid Hormone as a Stimulus to Mast Cell Accumulation In Bone," Calc. Tiss. Res., 5: 49-55 (1970							
	CZ1	Morrow, J.D., et al., "Release of markedly increased quantities of prostaglandin D2 in vivo in humans following the administration of nicotinic acid," Prostaglandins, Vol. 38(2): 263-274 (1989)							

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	CA2	Boushey, R. et al., "Adrenal Cortical Carcinoma," Curr. Treatment Op. Oncol., 2: 355-364 (2001)	
	CB2	Chines, A. et al., "Systemic Mastocytosis Presenting as Osteoporosis: A Clinical and Histomorphometric Study," J. Clin. Endocrinol. and Metab., Vol. 72(1): 140-144 (1991)	
	CC2	Singleton, V.L. and Rossi, J.A. "Colorimetry of Total Phenolics with Phosphomolybdic- Phosphotungstic Acid Reagents," Phenolics Determination, pp. 144-158	

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